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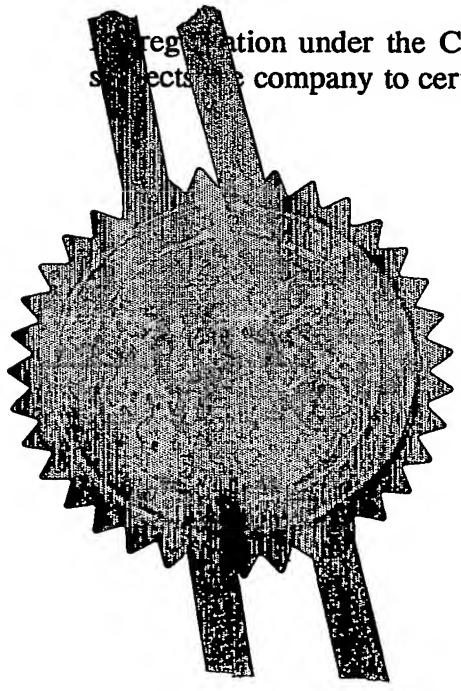

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Patents Form 1/77

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Request for grant of a patent

1. Your Reference: NSP/CLD/W659

17JUL02 E733674-4 D02846
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2. Application number: 17 JUL 2002 0216567.8

3. Full name, address and postcode of the or each Applicant

Country/state of incorporation (if applicable)

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4. Title of the invention: **IMPROVEMENTS IN AND RELATING TO THE APPPLICATION OF ELECTRICITY TO THE SKIN**

5. Name of agent: **APPLEYARD LEES**

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Patents ADP number: **190001**

6. Priority claimed to:

Country	Application number	Date of filing

7. Divisional status claimed from:

Number of parent application	Date of filing
-	-

8. Is a statement of inventorship and of right to grant a patent required in support of this application? **YES**

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	14
Claim(s)	3
Abstract	1 DM1
Drawing(s)	2+2

10. If you are also filing any of the following, state how many against each item

Priority documents	
Translation of priority documents	
Statement of inventorship and right to grant a patent (PF 7/77)	
Request for a preliminary examination and search (PF 9/77)	1 ✓
Request for substantive examination (PF 10/77)	
Any other documents (please specify)	

11. We request the grant of a patent on the basis of this application.

Signature: **APPLEYARD LEES**

Date: **16 July 2002**

Appleyard Lees

12. Contact: **Neil Parkinson- 0161 835 9655**

IMPROVEMENTS IN AND RELATING TO THE APPLICATION OF ELECTRICITY TO THE SKIN

Field of the Invention

This invention relates to apparatus and methods suitable for, but not limited to, the application of electricity to the skin so as to modulate nerves electronically.

Background to the Invention

Today, the therapeutic and diagnostic uses of electricity in medicine are widespread. Extensive literature exists on electro-therapy, the therapeutic application of electricity, which is suitable for treatment of a range of medical conditions.

TENS (Trancutaneous Electrical Nerve Stimulation) is the application of electrical pulses via electrodes placed on the skin of a patient, so as to produce a rather short-lived, localised region of analgesia. TENS devices typically utilise pulses of width 50-500μs, at a current of amplitude 0-50mA, delivered at a frequency of 80-100Hz. The TENS pulse is intended to be sufficiently long in duration to excite nerve fibres in the immediate vicinity of the electrodes to cause a painless tingling at low voltage (the voltage amplitude of TENS pulses that can be tolerated by a patient tends to be limited by the level of tingling sensation that can be comfortably endured).

TSE (Trancutaneous Spinal Electroanalgesia) improves upon TENS by providing a longer-lasting form of analgesia, that

is more generalised (i.e. not limited to the immediate vicinity of the electrical stimulation). TSE is, for instance, described within US 5,776,170 which describes the original research performed in relation to this treatment.

US 5,776,170 describes how, by applying a continuous series of electrical rectangular pulses to two electrodes, analgesic effects are induced in the central nervous system. The pulses used by the TSE stimulator are typically of amplitude 180 volts (compared with 35-50 volts of the TENS device), with a relatively narrow pulse width (1-10μs), at frequencies of typically 600-800Hz.

Figure 1 illustrates such a continuous pulse stream. Rectangular pulses 10, 12, 14 of width W, and amplitude V_p are delivered at regular predetermined intervals T. The pulse frequency is thus 1/T Hz (when T is expressed in seconds).

In electro-therapy, the efficacy of treatments is generally proportional to the voltage used. However, high voltages are normally both painful to the body, and damaging to tissues. As many electro-therapy devices are powered by batteries, the high energy usage associated with high voltages is also problematic.

Clinical efficacy is also a function of the frequency at which the pulses are delivered. However, whilst the body tissues are typically unharmed by the application of high frequency pulses, the heat generated in the electrodes utilised to apply the pulses can burn the tissues of the body. For instance, US, 5,776,170 describes how voltage

has to be decreased at high frequencies so as to reduce unwanted heating effects e.g. pulses of amplitude 150 volts can be utilised at a frequency of 5kHz, whilst the voltage has to be reduced to 25 volts at 150kHz.

It is an aim of embodiments of the present invention to overcome, or at least alleviate, one or more problems of the prior art, whether referred to herein or otherwise.

Statements of the Invention

In a first aspect, the present invention provides an apparatus for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body, the apparatus comprising a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide an intermittent series of electrical pulses.

Preferably, the apparatus further comprises a battery for providing power to said generating unit for the generation of said pulses.

Preferably, the apparatus further comprises at least two electrodes arranged for connection to said generating unit, for supplying electrical pulses to respective locations on the patients body.

Preferably, in said intermittent series of electrical pulses, the ratio of the time period for which no pulses are being provided to the time period for which pulses are being regularly provided is within the range 1:3 to 1:20.

Preferably, the ratio is approximately 1:10.

Preferably, at least one pause occurs in said intermittent series of pulses at least once every second.

Preferably, the pause is of duration of at least 0.5 millisecond.

Preferably, the series of pulses comprises a plurality of spiked pulses.

Preferably, the series of pulses comprises a plurality of bipolar pulses having a positive voltage peak and a negative voltage peak, with the transition time between the positive and the negative peak being at least 70% of the pulse width.

Preferably, the transition time is at least 95% of the pulse width.

Preferably, the width of the pulses in said series lies within the range 1 to 30μs.

Preferably, the pulses have a peak amplitude lying within the range 50-450 volts.

Preferably, the pulses are delivered at a predetermined frequency, said frequency lying within the range 100Hz to 250kHz.

Preferably, said apparatus is for supplying electrical pulses to two or more locations on the patients body overlying the central nervous system, such that the pulses

induce analgesic effects in the central nervous system, whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all.

In another aspect, the present invention provides an apparatus for applying an intermittent series of electrical pulses to the body of a patient substantially as described herein with reference to Figures 2 to 5.

In a further aspect, the present invention provides a method for applying electrical pulses to a patients body by utilising at least two electrodes at respective locations on the patients body, the method comprising applying an intermittent series of electrical pulses.

Brief Description of the Drawings

For a better understanding of the invention, and to show how embodiments of the same may be carried into effect, reference will now be made, by way of example, to the accompanying diagrammatic drawings in which:

Figure 1 illustrates a typical pulse train of a known TSE device;
Figure 2 illustrates an intermittent series of pulses in accordance with a first embodiment of the present invention;
Figure 3 illustrates a pulse shape in accordance with a second embodiment of the present invention;
Figure 4 is a schematic diagram of a device suitable for producing pulses in accordance with an embodiment of the present invention; and

Figure 5 illustrates the waveforms at various points in the device shown in Figure 4.

Detailed Description of Preferred Embodiments

By providing an intermittent series of pulses, rather than the continuous series of pulses utilised by the prior art, high frequency electrical signals can be applied to a patient without a significant build up of heat in the electrodes. Thus, by using an intermittent series of electrical pulses, for a given pulse frequency, higher voltages can be utilised without the electrodes burning the skin of the patient. Alternatively, for a predetermined pulse voltage amplitude, higher frequencies can be achieved without damaging tissues.

Further, as the number of pulses delivered in any given interval is reduced compared with a continuous series of pulses, then for a given pulse shape, amplitude and frequency, it will be appreciated that the power required is reduced. Thus, there is an improvement in battery life.

Initial trials have indicated that, despite the number of pulses being reduced due to the intermittent nature of the pulse series, clinical efficacy is not decreased compared with a similar continuous pulse series.

Figure 2 illustrates such an intermittent series of pulses. The series comprises a number of substantially uniformally sized and shaped pulses 110, 112, 114, 116, 118. The pulses are each of width W, with the spacing between each pulse in the series being normally T_1. The

pulses have an amplitude of V_p volts, and in this instance are substantially rectangular in shape. The intermittent series is achieved by providing a pause of temporal duration T_2, during which there are no pulses in the sequence. Preferably, the pause is an integral number of the pulse repeat period T_1 (i.e. $T_2 = n \times T_1$, where n is any integer). Figure 2 illustrates the case where $T_2 = 3T_1$, with the 3 dashed pulse shapes 216, 218, 220 indicating those pulses that have effectively been removed from the pulse sequence by the presence of the pause.

In order for nerve modulation to take place, it is desirable that the width W of the pulses lies within the range 1-30μs. Preferably, the pulses have a peak amplitude (V_p) within the range of 50 to 450 volts. Preferably, the pulses are delivered at a predetermined frequency (i.e. $1/T_1$) lying within the range 100Hz to 250kHz. The intermittent series of pulses effectively comprises blocks of pulses delivered at the predetermined frequency ($1/T_1$), with the blocks separated by pauses of duration T_2.

It will be appreciated that the repeat frequency of the pauses can be varied, however it is preferable that the total time period for the pause (i.e. the time period for which no pulse is being provided) compared with the average block length of the pulses (i.e. the time period for which pulses are being regularly provided) lies within the range 1:3 to 1:20. Preferably, the pauses are of duration of at least 1 millisecond (i.e. T_2 = 1ms).

Experiments have indicated that an intermittent pause timed at 1.3 milliseconds has no effect on clinical

efficacy, but it is anticipated that pauses for longer duration will also be effective, and have either no, or comparatively little effect upon the clinical efficacy. It will be appreciated that in a signal of 2500Hz, a pause of 1.3ms is over three times the length of the electronic pulse cycle (i.e. the pulse repeat time, T_1), whilst in a signal operating at 20000Hz, it is over 25 times the length of the electronic pulse cycle.

Whilst in the above embodiment, rectangular shaped pulses have been illustrated, it has been discovered that spiked pulses (i.e. pulses with very little signal duration at maximum amplitude) are particularly effective. Such pulses preferably also have relatively fast rise and fall times. This results in the pulse width W being relatively short compared to the length of the pulse cycle (e.g. W is less than 20% of T_1, or more preferably W is less than 10% of T_1, or even less than 5% of T_1). Spiked pulses are believed to be particularly efficient, as they allow relatively high voltages to be utilised for a given pulse power compared with a rectangular shaped pulse.

Surprisingly, bipolar pulses (i.e. pulses that have both a positive and a negative voltage peak) with a relatively fast transition from zero volts to a first peak in the pulse, and a relatively fast transition from the final peak in the pulse back to zero volts, but with a relatively gradual transition from the first peak of the pulse to the second peak of the pulse have been shown to be extremely effective. In trials, such pulses appear to have a strong relaxation effect upon patients.

The efficacy of the treatment also appears to be related to the pulse width, with wider pulses providing more effective treatment, presumably due to the increase in the total electrical power that can be applied to the patient. By utilising bipolar pulses as described above, the pulse width can be increased dramatically compared with the pulse width of a rectangular pulse. For instance, typical rectangular pulses are limited to a width of about 4μs, as longer rectangular pulses lead to a tingling feeling within the patient. However, using bipolar pulses, longer pulse widths can be comfortably utilised on a patient e.g. pulses of widths of up to 30μs, although preferably within the range 10-20μs

Figure 3 illustrates two such identical bipolar pulse shapes, with in this instance the first peak in the pulses being the positive voltage peak. The pulse cycle is again of length T_1, with the overall pulse width being W. The peak to peak voltage is shown as V_{pp}, with in this instance both the positive and the negative peaks being of similar amplitude. It will be seen that the pulse can be characterised by three time periods (W_1, W_2, W_3), where $W = W_1 + W_2 + W_3$. The initial transition from zero volts to the first peak voltage (in this case, the rise time of pulse) is of duration W_1, the transition time from the first pulse peak to the second pulse peak is of duration W_2, and the transition from the second pulse peak back to zero volts is of duration W_3.

It is desirable that W_1 and W_2 are both relatively quick compared with the overall pulse width W i.e. $W_1 + W_3 \leq 0.3W$, and more preferably $W_1 + W_3 \leq 0.95W$. In this example, $W_1 = W_3$. Preferably, the voltage constantly

changes during the transition time W_2, and preferably the change is at a constant rate.

Figure 4 illustrates an apparatus 300 suitable to automatically produce an intermittent series of pulses. The apparatus is powered by a battery 310, supplying a predetermined voltage of "a" Volts.

The apparatus can be envisaged as being in four distinct portions: a continuous fast pulse generator 330; a modulation waveform generator 320, 340; the output pulse shaping unit (360, 370, 350, 380); and the output electrodes 390a, 390b.

Figure 5 illustrates the waveforms at points marked A, B, C and "output" in the apparatus schematically shown in Figure 4.

The continuous fast pulse generator 330 is arranged to generate a continuous sequence of pulses at the desired, predetermined output pulse frequency. The pulses are substantially of width W. In this instance, the output waveform is of similar shape to that illustrated in Figure 3, but with a negative first pulse; the pulse width generated by the continuous fast pulse generator is thus substantially equal to W_2, rather than W. The waveform A is provided at one input to an OR logic gate 340.

The modulation waveform generator 320 is used to generate a waveform suitable for amplitude modulating the continuous fast pulse generator output, so as to obtain the desired pauses in the pulse series. In this instance, due to the particular implementation of the apparatus, the

output of the modulation waveform generator is in fact the inverse of the desired amplitude modulation envelope. Consequently, the waveform B output by the modulation waveform generator 320 is at logic 1 during the desired pause interval (i.e. indicated by T_2 in Figure 2), and at logic 0 for the remainder of the time.

The OR gate 340 combines the two input waveforms A, B using the logical OR operation, and outputs waveform C.

The high voltage switch 350 is operated by the output of the OR gate 340 i.e. by waveform C. The high voltage switch 350 controls the charging and discharging of capacitor 370.

The capacitor 370 charges up via the operation of a transformer 360, which acts to step up the voltage from the battery power supply 310.

The high voltage switch 350 operates so as to allow the capacitor 370 to be charged up to a relatively high voltage (i.e. approximately the desired peak voltage of the output pulse), with the capacitor being subsequently discharged to the output electrodes 390a, 390b. This output voltage discharge can occur through capacitor 380, which can act to differentiate the signal resulting from the discharge of capacitor 370, and so obtain the desired waveform.

The output voltage waveform is provided across electrodes 390a and 390b, before application to the body of the patient.

In use, in order to obtain TSE, the electrodes are normally applied to the surface of a body overlying the central nervous system, such that analgesic effects tend to be effected in the central nervous system whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all. If desired, the electrodes could be implanted within the body, including within the skin, but it is more preferable that they are designed to simply be placed in contact with the skin surface. Typically, the electrodes are spaced apart by a distance of around 10cm, and are always over the central nervous system, irrespective of the location of the pain.

In the context of this invention, the term "central nervous system" should be interpreted to include the brain and the spinal cord, and also include the other neural tissues which may otherwise be classed as part of the peripheral nervous system, but are in close anatomical proximity to the central nervous system, such as the ganglia, autonomic or somatic, such as the dorsal root ganglia.

It will be appreciated that the above description is provided by way of example only, and that various other waveforms, and apparatus suitable for producing such waveforms, would be understood as falling within the scope of the present invention. Further, whilst the apparatus has been described in terms of being utilised for TSE, it will be appreciated that other, similar apparatus can make use of the present invention. Electrodes of such apparatus need not be located over the central nervous system when in use.

For instance, evidence suggests that locating the electrodes of a pulse generator on either side of the carotid bodies of a patient can assist in management of the cardio vascular system. Applying this type of pulse as described herein at an operating frequency of approximately 20kHz, with a peak to peak voltage of between 250-300 volts has been shown to effect cardio-vascular system, including altering the pulse rate of a patient.

Further, evidence suggests that application of this type of pulse to patients who suffer from epilepsy appears to reduce the number of epileptic fits.

Throughout this document, the term patient is not limited to humans, but can be understood as relating to any vertebrate species including mammals. This can include animals such as cats, dogs and horses.

Whilst the preferred embodiment has been described as being powered by a battery, it will be appreciated that any power source could be utilised to power the device, including a power supply comprising a transformer, and suitable for connection to a mains electricity supply.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS:

1. An apparatus for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body, the apparatus comprising a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide an intermittent series of electrical pulses.

2. An apparatus as claimed in claim 1, further comprising a battery for providing power to said generating unit for the generation of said pulses.

3. An apparatus as claimed in claim 1 or claim 2, further comprising at least two electrodes arranged for connection to said generating unit, for supplying electrical pulses to respective locations on the patients body.

4. An apparatus as claimed in any one of the above claims, wherein, in said intermittent series of electrical pulses, the ratio of the time period for which no pulses are being provided to the time period for which pulses are being regularly provided is within the range 1:3 to 1:20.

5. An apparatus as claimed in claim 4, wherein said ratio is approximately 1:10.

6. An apparatus as claimed in any one of the above claims, wherein at least one pause occurs in said intermittent series of pulses at least once every second.

7. An apparatus as claimed in claim 6, wherein said pause is of duration of at least 0.5 millisecond.

8. An apparatus as claimed in any one of the above claims, wherein said series of pulses comprises a plurality of spiked pulses.

9. An apparatus as claimed in any one of the above claims, wherein said series of pulses comprises a plurality of bipolar pulses having a positive voltage peak and a negative voltage peak, with the transition time between the positive and the negative peak being at least 70% of the pulse width.

10. An apparatus as claimed in claim 9, wherein said transition time is at least 95% of the pulse width.

11. An apparatus as claimed in any one of the above claims, wherein the width of the pulses in said series lies within the range 1 to 30μs.

12. An apparatus as claimed in any one of the above claims, wherein said pulses have a peak amplitude lying within the range 50-450 volts.

13. An apparatus as claimed in any one of the above claims, wherein said pulses are delivered at a predetermined frequency, said frequency lying within the range 100Hz to 250kHz.

14. An apparatus as claimed in any one of the above claims, wherein said apparatus is for supplying electrical pulses to two or more locations on the patients body overlying the central nervous system, such that the pulses induce analgesic effects in the central nervous system, whilst stimulating peripheral nerves that lie between the

electrodes and the central nervous system to a lesser extent or not at all.

15. An apparatus for applying an intermittent series of electrical pulses to the body of a patient substantially as described herein with reference to Figures 2 to 5.

16. A method for applying electrical pulses to a patients body by utilising at least two electrodes at respective locations on the patients body, the method comprising applying an intermittent series of electrical pulses.

ABSTRACT

IMPROVEMENTS IN AND RELATING TO THE APPLICATION OF ELECTRICITY TO THE SKIN

An apparatus is described for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body. The apparatus comprises a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide an intermittent series of electrical pulses.

[Figure 2]

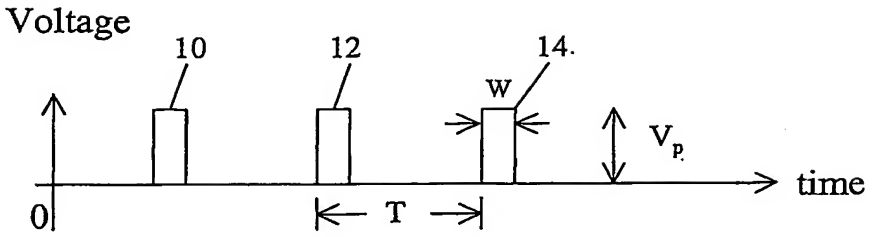

FIG. 1

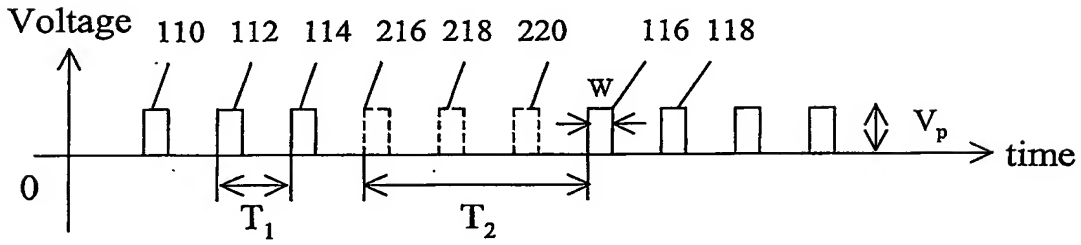

FIG. 2

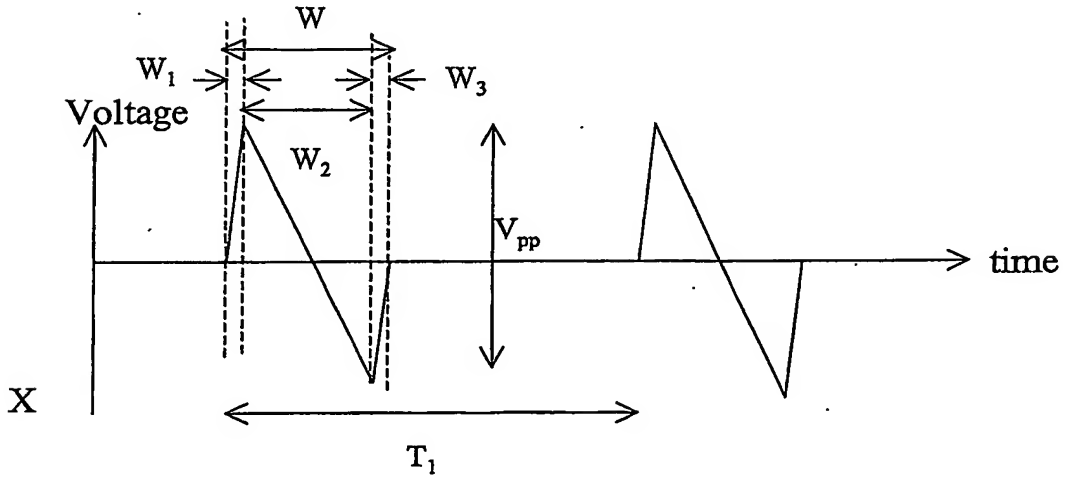

FIG. 3

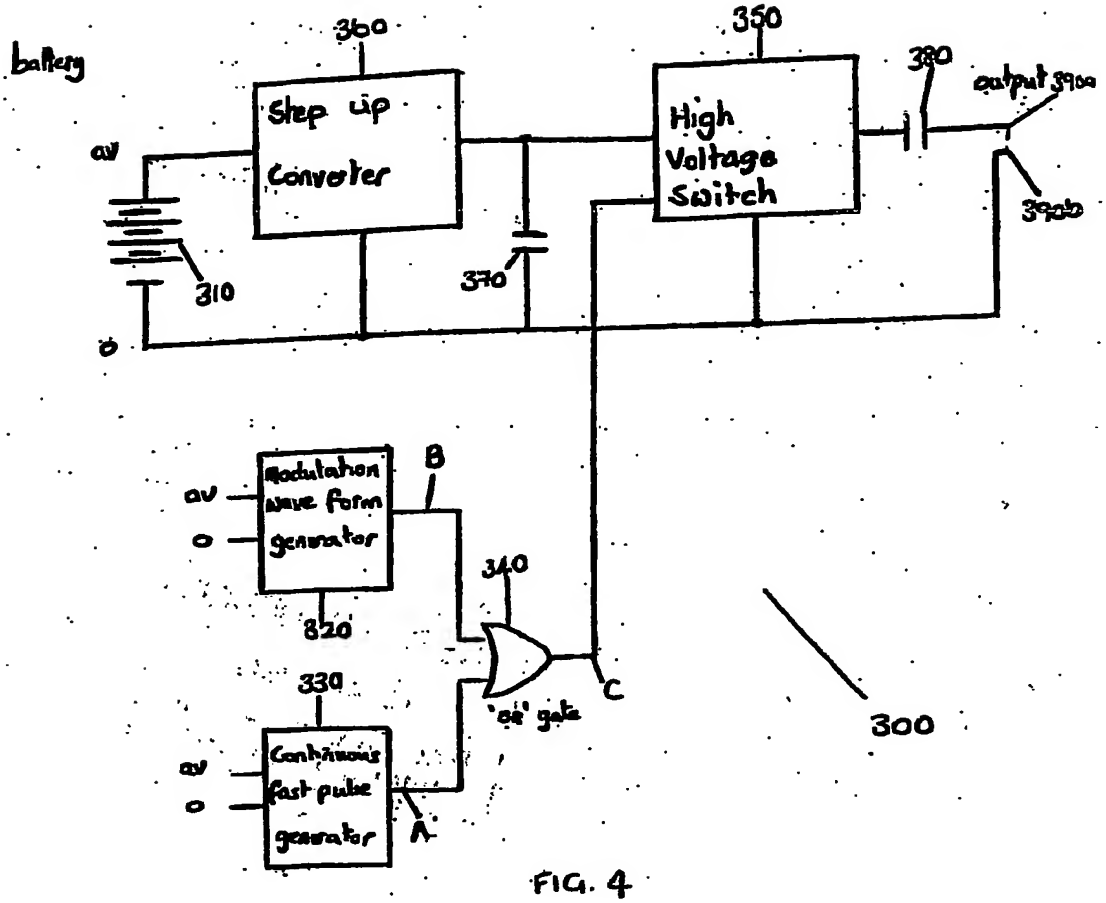
battery
360
Step up
Converter
350
High
Voltage
Switch
380
output 390a
390b
av
0
310
370
Modulation
wave form
generator
B
820
340
330
Continuous
fast pulse
generator
A
'or' gate
C
300

FIG. 4

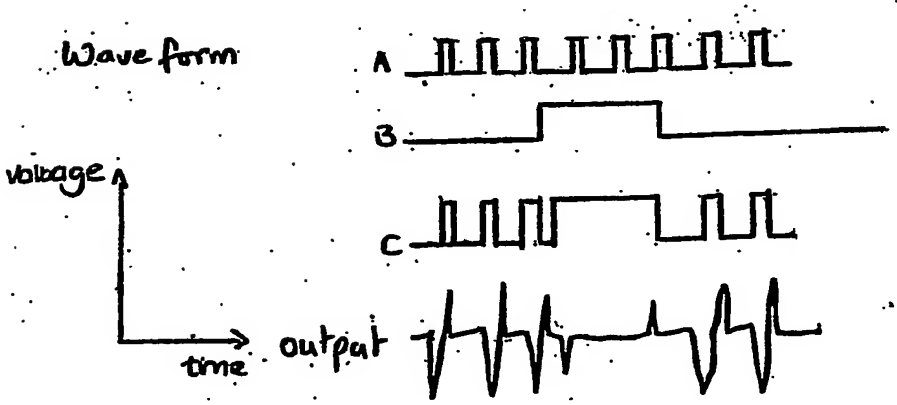
Wave form
A
B
C
voltage
time
output

FIG. 5